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Moulding serving for pharmaceutical uses and method for producing the moulding

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The invention firstly relates to a moulding serving for a pharmaceutical use, such as a stopper for pharmaceutical bottles, a protective cap for medical syringes or a sealing element for a pharmaceutical container.

The invention also relates to a method for producing such a moulding.

Mouldings of this type often have aesthetic defects. Such irregularities, impairing the visual appearance, may occur in the form of frayed fibres and primarily form also in the region of the injection point. Therefore, there has already been a change in the way in which stoppers for instance are produced, arranging the injection point in a concealed position, for example in the region of a cavity within a stopper. Such an arrangement entails difficulties, however, since the nozzle of the injection device also requires a certain amount of space. Flow defects at sealing locations, for example at a flange-like edge region of such a stopper, facing the end edge of the flanges, may even cause sealing problems.

In addition, mouldings of this type also have to meet high technical requirements in other respects. For instance, during piercing, if at all possible there must not be any crumbling away of parts of the material, which could be entrained. Piercing must also be possible without any hindrance. In the case of protective caps, for instance, good material cohesion is also required, important also for instance in the case of the other configurations of the moulding.

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On this basis, the invention is concerned with the object of providing a moulding suitable for

pharmaceutical uses which is as homogeneous as possible and as free from defects as possible. Furthermore, the invention is concerned with the object of providing a production method suitable for this.

With regard to the moulding, the object is achieved firstly and substantially by the respective subject matter of Claims 1 and 2, it firstly being of significance, Claim 1, in addition to the features already specified, that the moulding consists, at least in a subregion, of a thermoplastic elastomer material with a mineral filler content of 30% or more and this subregion has a hot-runner injection point which is formed as a smooth-surfaced mark. In addition, Claim 2, it is also of significance that, in the case of a second part of the moulding, the latter consists of a different plastics, for example a conventional injection-moulding plastics, such as PP, PE or the like, which is then used to inject over the injection point of the first subregion. In such a case, the injection point of the subregion formed from the flexible elastomer material in particular can then also be formed as a hot-runner injection point, which is then, again preferably, also formed as a smooth-surfaced mark. According to the invention, it has been recognized that a thermoplastic elastomer material with a mineral filler content of 30% or more is suitable for meeting the material requirements of pharmaceutical mouldings of this type. This is so at least when, in the case of outward exposure on the moulding, the injection point is formed by a hot-runner injection point and a smooth-surfaced mark is created. Disturbing streaking or instances of material unevenness, in particular in the region of the injection point, can no longer be found. Nevertheless, such a moulding can be efficiently produced by customary injection-moulding processes, but with hot-runner injection. It is preferable in this context that the mark which is created on the moulding by the

hot-runner injection point goes over into the moulding wall surrounding it without being offset outwards. In particular, it is preferred for the smooth-surfaced mark to go over into the moulding wall surrounding it in a co-planar manner. Furthermore, however, it may also be recommendable in special cases for the mark to be raised with respect to the moulding wall surrounding it, that is to say it is offset outwards. This is so for example if, as is the aim also of Claim 2 explained above, the two-component injection-moulding process is being used or the moulding consisting of the elastomer material is part of a multi-part article, in which the injection point is covered by a further part or is even encapsulated therein. This is so because a raised mark may also be recommendable for positive engagement in a further part.

The moulding may altogether be of a multi-part form, by being produced for instance in the multi-component injection-moulding process, it being possible for the individual parts to adhere to one another directly in the manner of welding, or else to be separable or separate from one another after completion of the injection process. In such a multi-part moulding, such as that described further below in detail, the part consisting of thermoplastic elastomer material is then a subregion of the same.

Furthermore, it is also preferred for such a moulding, or the corresponding subregion of the moulding, to be formed with thick walls, at least in the region of the injection point. Thick walls are understood here in particular with regard to a length of the flow path of the injected material in relation to the wall thickness. The length is measured from the injection point. Here, furthermore, a mean value over the entire moulding is used as the wall thickness. If a value of < 5 is obtained, the walls are considered to be thick in the sense of the present patent application

The moulding, or the corresponding subregion of the moulding, takes the form of a homogeneous body. The specified mixture produces an elastomeric structure with good piercing behaviour. The requirements for after-sealing, for instance in the case of pulled-out cannulas, are also satisfied.

The added mineral filler content acts with a flow-retarding effect, which advantageously supports an aimed-for uniform distribution of the plastics in the course of the injection process. The hot-runner injection, which is preferably also performed in a central region, or preferably also on an outer surface, that is to say not in a cavity region of the moulding, likewise promotes balanced distribution of the plastics in the course of an injection-moulding operation. The predominantly thick-walled formation of the moulding, or the corresponding subregion of the moulding, also leads to substantially the same situation with respect to shrinkage, although this is comparatively very slight in the case of the specified material. The filler is preferably a silicate. In may be, for example, magnesium silicate (tallow). This filler has the effect of advantageous flow retardation. Nevertheless, in absolute terms, the filling of a corresponding mould cavity takes place very quickly. With the customary size of stoppers concerned here, for instance, or other articles of a comparable size, the filling time is about 0.1 second. There is moreover, with respect to the thermoplastic elastomer material described, to which a plasticizer is possibly added, a surprisingly low dependence of its properties on the temperature. The filling of a cavity can be achieved to the greatest extent independently of the filling temperature, without the occurrence of a so-called spaghetti effect. The Shore hardness A lies between 45 and 60, preferably at 55.

More specifically with respect to a stopper concerned here, with regard to good penetrability with the cannula of a syringe it is provided that the stopper top has a central region of lesser wall thickness and an edge region of greater wall thickness, measured in the vertical direction. In the use in question, the edge region is enclosed by a flanged cap of a corresponding infusion-bottle fastener. Possibly enclosed with a clamping action.

The closure top is connected downwards in the vertical direction with a stopper collar. This stopper collar likewise preferably has, in any event in its initial region connected with the stopper top, a greater wall thickness than the stopper top in its central region. At the same time, the stopper collar is consequently preferably connected with the region of greater wall thicknesses of the edge region of the stopper. It is further preferred for the hot-runner injection to be performed with regard to the injection-runner closure with a ram-like needle head, the planar end face of the needle head in the shut-off state of the injection mould going over in a co-planar manner into the surrounding nozzle wall, forming part of the wall of the moulding. It can correspondingly also be stated that the smooth-surfaced injection point, that is to say the injection area, goes over in a co-planar manner into the surrounding surface of the moulding. A smooth-surfaced mark of the ram-like needle head is obtained on the moulding, effectively avoiding even extremely small instances of roughness or fissuring. The moulding is produced without any secondary finishing. The said configuration has the particular advantage in the case of the stopper that no fractionation particles, caused for instance by inaccuracies, can be carried away through the cannula and get into the bottle. The fully formed smooth surface consequently exists also and in particular with

respect to the injection point itself, approximately the size of a pin head.

A further embodiment of such a moulding for pharmaceutical uses is a protective cap for medical syringes. This protective cap is fitted over the cannula of a syringe, in order to protect the latter with regard to instances of mechanical impairment or else soiling. In a corresponding way, such a protective cap also consists of a thermoplastic elastomer material which has a mineral filler content of 30% or more. In the region of a cap hat of the protective cap there is a hot-runner injection. Here, the same properties are achieved, in particular with regard to the exterior of the protective cap, as already explained with respect to the stopper. With regard to the material, the moulding formed as a protective cap can also contain a proportion of plasticizer. Here, too, the hot-runner injection is preferably performed centrally, in the region of the tip of the cap hat. Consequently, the explanation as provided before in detail with regard to the ram-like needle head, which is preferably used on the injection-moulding machine side, and the advantages achieved by this, also apply with respect to the protective cap.

A further article which may be embodied by such a moulding serving for pharmaceutical uses is a sealing element, as used in the case of so-called "bottle-pack" bottles. In this respect, reference is made in particular to the disclosure of German Patent Applications 195 00 460 and 196 20 196, the contents of which are hereby also incorporated in full, also for the purpose of including features of these prior publication in claims of the present patent application. Such a sealing element customarily has a peripheral flange of a smaller wall thickness or, on the upper side and/or underside, a peripheral groove associated with the edge and a central region of

greater wall thickness. Here, too, the injection preferably takes place centrally in the upper outer surface. Moreover, the geometrical features described also apply here, for instance with regard to the thickness of the walls, and the features regarding the purity and freedom from streaks, as already explained before with respect to the moulding in general and the other uses. In particular, such an article may also be produced in the multi-component injection-moulding process, the one subregion, for instance the subregion of rigid plastics forming the outer cap, then forming the mould (again at least partially) for the subsequently injected elastomer-material subregion. It is also possible, however, to adopt the reverse procedure. In particular in the latter case, it is possible, and may even be appropriate, to produce the hot-runner injection point in such a way that it is raised with respect to the surrounding moulding wall of elastomer material, but in the end depressed with respect to the moulding wall of a second subregion of another plastics component, in particular a rigid plastics component.

The invention also relates to a method for producing a moulding serving for pharmaceutical uses, such as for instance a stopper for pharmaceutical bottles, a protective cap for medical syringes or a sealing element for pharmaceutical containers. In this respect, it is provided in one embodiment that a thermoplastic elastomer material with a 30% or more admixed mineral filler content is used as the material and that a central hot-runner injection is performed in the region of a moulding top or a moulding tip. In a further embodiment, it is provided that in any event a subregion is produced from a thermoplastic elastomer material with a mineral filler content of 30% or more and this subregion is configured by an injection having an injection point, which injection point is injected over by another plastics, forming a second subregion of

the moulding. Used here in particular is a customary plastics for moulded parts, such as for instance PP, PE etc. To be specific, as before in respect of the features constituting the subject matter, a corresponding filler content in per cent by weight is provided. Advantageously, a proportion of plasticizers is also added to the thermoplastic elastomer material. With regard to a stopper, it may be provided that the central hot-runner injection is performed in the region of the stopper top, formed predominantly with a thick wall. The stopper collar may also be formed with a greater wall thickness than the stopper top in its central region. With respect to a seal, the injection may be performed in the upper outer surface, preferably centrally there. It is further preferred, in respect of all the embodiments, that the hot-runner closure can be used in the form of a ram-like needle head, the planar end face of which in the shut-off state goes over into the surrounding nozzle wall, forming part of the wall of the moulding, in a co-planar manner or offset into the interior of the moulding with respect to the said nozzle wall. This makes it possible to achieve a smooth-surfaced injection point and for the injection area of the injection point to go over into the surrounding moulding wall in a co-planar manner or offset in terms of depth.

When forming a protective cap for medical syringes in the plastic injection-moulding process specified above, a solid cap hat and a comparatively thin-walled cap neck is moulded. In an advantageous way, the hot-runner injection takes place centrally on the cap hat. Otherwise, from a production engineering viewpoint, the same features as also already described above with respect to the production of the stopper or the seal are preferred.

The subject matter of the invention is explained in more detail below on the basis of two exemplary embodiments illustrated in the drawing, in which:

Figure 1 shows a stopper produced in the plastics injection-moulding process in side view, representing the first exemplary embodiment;

Figure 2 shows the plan view of this;

Figure 3 shows the view from below;

Figure 4 shows a vertical section through an infusion bottle with associated stopper, fastened by fitting on a flanged cap;

Figure 5 shows a section through the mould cavity region of an injection-moulding device, unfilled;

Figure 6 shows an identical representation, but with the mould cavity filled;

Figure 7 shows a protective cap produced in the plastics injection-moulding process for a syringe, in side view;

Figure 8 shows a vertical section through the protective cap, greatly enlarged, together embodying the second exemplary embodiment;

Figure 9 shows in side view a sealed container, as used as an infusion bottle;

Figure 10 shows a cross-section through the article according to Figure 9, in the region of the closure device in a first embodiment;

Figure 11 shows a representation according to Figure 10 of a second embodiment;

Figure 12 shows an enlarged cross-sectional representation of the injection region with a needle head offset into the interior with respect to the surrounding moulding wall;

Figure 13 shows a representation according to Figure 6, but with an injection point offset outwards with respect to the surrounding moulding wall; and

Figure 14 shows a representation of the article according to Figure 11, the injection point of the elastomer-material subregion being raised with respect to the surrounding moulding wall and at the same time accommodated in a further subregion of the moulding.

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The stopper 1 represented in Figure 1 and the seals 38, 39 represented in Figures 10 and 11 and the protective cap 2 shown in Figure 7 are produced in the plastics injection-moulding process.

A thermoplastic elastomer material of rubber-like elasticity and nevertheless adequate inherent rigidity is used.

The stopper 1 can be associated with a bottle 3, protecting its contents. This is a bottle 3 which can be used in the pharmaceutical sector, such as for example an infusion bottle.

The bottle 3 represented in Figure 4 shows how the stopper 1 is disposed in relation to the neck 4 of the bottle 3 and secured by a metallic flanged cap 5. The latter also accommodates an inner cap 6. The flanged

cap 5, to be designated in contrast as the outer cap, is rolled on, going around a shoulder 7 of the bottle neck 4. The flanging location has the reference numeral 8.

The bottle 3 consists of glass, for example.

The stopper 1 takes the form of a hollow stopper. The latter fits in a sealing manner in a substantially cylindrical mouth 10 of the neck 4. The cavity of the hollow stopper 9, opening towards the space inside the bottle, has the reference numeral 11.

The stopper 1 takes the form of a pierceable closure. For this purpose, the substantially centrally lying piercing region 12 of the stopper 1 is exposed. Details in this respect are provided by the German Patent Application 100 05 833, which is not a prior publication. The disclosure content of this patent application is hereby incorporated in full, also for the purpose of including features of the patent application referred to in claims of the present patent application.

The piercing region 12 represents a stopper top 13, which continues on the bottle side into a stopper collar 14.

Figure 4 reveals for example that the stopper top 13 has a central region, representing the piercing region 12, of lesser wall thickness x and an edge region 15 of greater wall thickness y. The ratio of X : Y is around 3 : 4 and in Figure 5 more like 2 : 3, and is based on a slightly smaller central accumulation of material, which favours the piercing behaviour.

Taking into consideration the conditions in Figure 5 for example, it becomes clear that the stopper collar also has, at least in its root region with respect to

the stopper top 13, a greater wall thickness z than the stopper top 13 in its central region, that is the piercing region 12.

In spite of these partial differences in wall thicknesses, the stopper 1 as a whole is of a predominantly thick-walled form. This altogether sturdy moulding has a good final strength and is also stable enough for the ejector 16 of the injection-moulding device 17, partially represented in Figures 5 and 6.

The protective cap 2 represented in Figures 7 and 8 for syringes in the medical sector is designed in terms of its walls with other prime considerations taken into account. For instance, the long, externally cylindrical body has a cap hat 18 of greater material accumulation, which cap hat is continued in the longitudinal direction into a thin-walled cap neck 19. The wall of the cap neck 19, protectively surrounding the cannula, is hollowed in a stepped manner on the inside; the corresponding cavity 20 goes over into an extremely narrow zone 21, designed as a piercing zone for protecting the proximal end of the needle body and keeping it closed.

The neck end has the least wall thickness. In this region, the moulding, kept substantially cylindrical over its circumferential wall, has a prominent annular shoulder 22.

The injection point lies at the exposed point of the cap hat 18, that is at the tip of the cap hat. The quite thick-walled top is rounded in a flat-convex manner.

Represented in Figure 9 is a transfusion bottle 40, which has an eyelet 41 on its base, for hanging the

transfusion bottle 40 upside-down. The bottle head 42 then faces downwards.

The bottle body consists of plastics, for example PE, with a penetrable wall thickness, for penetration by means of cannulas or spikes, for example.

This closure wall of the bottle 40 itself is not represented in detail. Fitted over the closure wall is a cap 43, as represented in detail in different embodiments in Figures 10 and 11. Disposed within the cap 43 is a moulding 44, which represents a seal. The seal is pierceable and is located in front of the unrepresented closure wall of the bottle 40. In the case of the exemplary embodiment of Figure 10, the seal 44 has a peripheral flange 45, which rests on an associated flange 46 of the cap 43. The flange 45 has a much smaller wall thickness than a central region of the seal 44.

In the case of the exemplary embodiment of Figure 11, the seal 44 has piercing regions 47, which are reduced in thickness. Starting from the upper side and underside, hemispherical recesses 48 are formed lying back-to-back. In the region of their greatest vertical extent, the recesses 48 have the effect that the thickness of the seal 44 is reduced to approximately 1/5 in comparison with its greatest thickness.

In the case of the exemplary embodiment of Figure 11, grooves 49 are also provided peripherally on the upper side and underside of the seal 44, whereas the edge region 50 again has a vertical extent such as that also of the central region of the seal 44, in which the injection point is also preferably located on an outer surface.

The mouldings in the form of the stopper 1, the protective cap 2 and the seals 44 are not only each

produced in the plastics injection-moulding process, but also using the same material. A thermoplastic elastomer material (TPE) is used. The material contains an admixture of mineral filler. The filler content in this respect is 30% or more. Magnesium silicate is preferably used as the filler. The mineral filler has a certain flow-retarding property, with the result that a flow cohesion occurs when filling the mould cavity 23 of the injection-moulding device 17. The special moulding features are explained with reference to Figures 5 and 6, primarily on the basis of a stopper as an example:

The injection point A (cf. for instance Figures 6 and 13) of the hot-runner injection is denoted on the moulding (cf. for example Figures 2, 4, 7, 8, 14) by 24. It may lie centrally on the protective cap 2 and preferably lies centrally on the stopper 1, as also in the case of the seals 44. This achieves the effect of a uniform distribution at high flow rate. Aesthetic defects do not occur. There are not even any visual irregularities such as colour deviations. Furthermore, customary injection moulds can be used. In this case, the cavity filling is largely temperature-independent. It can between 200 and 280°C, without any major differences in quality being evident.

The central access of the injection moulding compound M (cf. Figures 5, 6, represented using the example of injection of a stopper), takes place via a nozzle 25 of an upper mould part 26. The associated lower mould part is denoted by 27. The mould cavity 23 is proportionately distributed. At the centre of the lower mould part 27 there is a vertically movable mould projection, represented by the ejector 16.

The filling process is in each case valve-controlled. For this purpose, a vertically movable needle 28 is located in the upper mould part 26. Its needle head 29

enters the mouth of the nozzle 25 in a closing manner (cf. Figure 5).

The ram-like needle head 29 of the hot-runner injection A has a planar end face 30. The end face extends in the shut-off state of the hot-run injection A in a co-planar manner into the nozzle wall 31, forming part of the moulding wall and surrounding the mouth of the nozzle 25. The moulding wall may be the upper side of the stopper top 13 of the stopper 1 or the corresponding surface of the cap hat 18 of the protective cap 2 or of the seal 38 or 39 of Figures 10 and 11.

Referring to Figures 5 and 6, it can be gathered that a horizontal gap exists between upper mould part 26 and lower mould part 27, forming a first air discharge 32 when injected material, that is the injection-moulding compound M, forces its way in. A second air discharge 33 exists in the vertical direction, to be precise in the form of an annular gap between the ejector 16 and a receptacle of the lower mould part 27 shaped for the said ejector to fit. As a result, complete filling of the mould cavity 23 is achieved in the time provided, without markings such as flow streaks or the like occurring on the outside of the moulding. The material emerging under pressure from the nozzle 25 is not separated by any blind hole in such a way that it cannot be vented. If the flow path represented in Figure 5 by arc lines B is taken as a basis, an escape of air from the end zones a and b represented would not be hindered because of the air discharges 32, 33 described. In the case of the articles according to Figures 7 and 10, corresponding pockets are also not possible. There, the displaced air escapes via the discharge corresponding to the first air discharge 32.

In the case of the article of Figure 11, it may again be favourable to provide a plurality of air discharges of this type in the mould.

With respect to the mouldings described, the list of requirements in terms of the material also take into account that such mouldings should be autoclave-resistant. They withstand temperatures of 120° over a relatively long period of time. In spite of the admixture explained, the material remains outstandingly suitable for injection moulding. The required compromise has been found. Moreover, plasticizer is also added to the thermoplastic elastomer material.

The needle 28 positioned centrally in the injection runner 35 is surrounded on the runner wall side by a heating element 36.

The nozzle wall 31 of the upper mould part 26 has in the case of the stopper 1 or a seal 44 an annular groove 37. The annular groove runs concentrically with respect to the nozzle 25, is of a triangular cross-section and acts on the upper side of the stopper top 13 as if it were a target ring 38 for the correct placement of the cannula or a spike.

Because of the described planarity of the end face 30 of the needle 28, there is a smooth detachment of the needle after demoulding, i.e. without leaving behind a rough mark of a sandy structure. To this extent, it is also not possible for projecting-out particles to pass, during use, through the cannula and enter the interior of the bottle 3. The mark represented in Figure 2 is on the one hand only emphasized for the purposes of the drawing. On the other hand, such a mark can also be obtained if the procedure corresponding to Figure 12 is followed. Here, in the shut-off state, the end face 30 of the needle 28 protrudes beyond the surrounding nozzle wall. In a corresponding way, on the moulding

the injection region is formed such that it is offset into the interior of the moulding. For example in the case of a needle diameter of 1.5 mm, the offset into the interior may total 0.3 mm. In this case, the needle tip may also be specifically formed such that it is firstly cylindrical and then has a convex end face, it being possible for the cylindrical region to be offset into the interior of the moulding by 0.05 mm for example, and for the convex end face region to be offset by a further 0.3 mm. Nevertheless, the smooth detachment, even free from pulled strands, is retained.

Customary drafts on the moulding have been taken into account.

Shown in Figure 13 is a representation according to Figure 6 in which the injection point A of the moulding, here the stopper 13, is formed such that it is offset outwards with respect to the surrounding moulding wall. It is evident that, in the shut-off state, the needle head 29 is withdrawn with respect to the surrounding nozzle 25 to the extent that a cylindrical projection of the moulding 13 is produced, remaining within the nozzle 25.

In the case of the embodiment of Figure 14, the article according to Figure 11 is produced in the two-component injection-moulding process, the injection point 24 being formed such that it is offset outwards with respect to the surrounding moulding wall, in a way corresponding to a mould-related design according to Figure 13. Following the moulding of elastomer material formed here as a seal 44, the surrounding cap 44 has been moulded, including a cap part formed here as projecting portion 51 and extending over the injection point 24. The feature that, when produced in the two-component injection-moulding process, the injection point 24 of the subregion of the (overall) moulding, which consists of thermoplastic elastomer

material, has the further subregion of the moulding of plastics of the second component extending over it is also significant, irrespective of how the injection point 24 is formed.

All disclosed features are (in themselves) pertinent to the invention. The disclosure content of associated/attached priority documents (copy of the prior application) is hereby fully incorporated into the disclosure of the patent application, also for the purpose of including features of these documents in claims of the present patent application.